UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
AT LOUISVILLE

MARILYN HILL 3145 Estes Lane Paducah, Kentucky 42003 Plaintiff, v. MERCK & COMPANY, INC. **SERVE:** C. T. Corp. System Kentucky Home Life Bldg. 239 S. Fifth Street, Ste. 1511 Louisville, KY 40202 Defendant.	)	CIVIL ACTION NO. 3:07--cv-320-JBC ***E-Filed***

COMPLAINT & JURY DEMAND

Comes the Plaintiff, Marilyn Hill, by and through her undersigned counsel, and for her Complaint against Defendant, Merck & Company, Inc. (hereinafter "Merck" or "Defendant"), hereby alleges as follows:

I. PARTIES

1. At all times relevant to this action, Plaintiff was a resident of Bardstown, Nelson County, Kentucky.

2. Defendant is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. The Defendant's principal office is located at One Merck Drive, Whitehouse Station, New Jersey.

3. Defendant was at all relevant times authorized to conduct business in the Commonwealth of Kentucky, and Defendant has regularly transacted business in the Commonwealth of Kentucky and continues to do so.

4. At all relevant times Defendant, through its agents, servants, employees and apparent agents was the designer, manufacturer, marketer, distributor and seller of FOSAMAX, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis, osteopenia, and Paget's Disease.

5. Defendant, either directly or through its agents, apparent agents, servants or employees, at all relevant times, sold and distributed FOSAMAX in the Commonwealth of Kentucky.

6. Defendant derives substantial revenue from pharmaceutical products used or consumed in the Commonwealth of Kentucky, including FOSAMAX.

7. Defendant expected, or should have expected, that its business activities could or would have consequences within the Commonwealth of Kentucky.

8. Defendant placed FOSAMAX into the stream of worldwide commerce and interstate commerce in the United States. It did so without adequate testing and with no warning that the use of this drug carried with it a risk of causing osteonecrosis of the jaw.

9. Plaintiff and others need continued medical monitoring to prevent or mitigate the future onset of osteonecrosis of the jaw or treat osteonecrosis of the jaw which has already manifested.

II. JURISDICTION AND VENUE

10. The amount in controversy in this action exceeds $75,000 exclusive of interest and costs.

11. The events or omissions which give rise to this complaint occurred in Nelson County, Kentucky.

12. This Court has original jurisdiction in this action pursuant to 28 U.S.C. §1332.

13. Venue is proper in this Court pursuant to 28 U.S.C. §1391(a)(2).

III. FACTUAL BACKGROUND

14. At all relevant times Defendant was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

15. In September 1995, the United States Food and Drug Administration ("FDA") approved Merck's compound alendronate for various uses, including the treatment of osteoporosis and Paget's Disease. Alendronate is marketed by Defendant Merck as FOSAMAX.

16. FOSAMAX falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class, such as Aredia and Zometa, are used as chemotherapy and as adjunct chemotherapy but are not included for use in non-cancerous conditions such as osteoporosis.

17. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. Alendronate is a nitrogenous bisphosphonate. The Physicians Desk Reference ("PDR") for FOSAMAX confirms that the molecule contains a nitrogen atom.

18. Beginning in the 1990s and extending into the 2000s, peer-reviewed articles and studies appeared throughout the medical literature reporting the frequent and common occurrence of osteonecrosis of the jaw in connection with the use of the

nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Merck knew or should have known that FOSAMAX, as a nitrogenous bisphosphonate, shared a similar adverse event profile to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

19. As a result of the extensive evidence presented in the medical literature, Merck new or should have known that bisphosphonates, including FOSAMAX, inhibit endothelial cell function. Similarly, Merck knew or should have known that Bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patients' mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

20. Merck also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turn into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

21. Dentists are now being advised by dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient taking FOSAMAX.

22. Shortly after Defendant began selling FOSAMAX, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that FOSAMAX shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Defendant failed to implement further study of the risk of osteonecrosis of the jaw relative to FOSAMAX. Rather than evaluating and verifying the safety of its product, FOSAMAX, with respect to osteonecrosis of the jaw, Defendant proposed

further uses of FOSAMAX, such as FOSAMAX-D, sought to extend the exclusivity period of FOSAMAX through 2018, and continued to aggressively market the drug.

23. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and even death.

24. Since FOSAMAX was released, the FDA has received a significant number of reports of osteonecrosis of the jaw among users of FOSAMAX.

25. On August 25, 2004, the FDA posted its ODS Postmarketing Safety Review on bisphosphonates—specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate (FOSAMAX). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.

26. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to intravenous bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonates, including FOSAMAX.

27. As a result, the FDA recommended and stated that the labeling for FOSAMAX should be amended by Defendant to specifically warn about the risk of osteonecrosis of the jaw. To this day, FOSAMAX labeling does not appropriately warn of the risk of osteonecrosis of the jaw.

28. Rather than adequately warning patients, and despite knowledge by the Defendant about substantial risk of osteonecrosis of the jaw in patients using FOSAMAX, Defendant continues to defend FOSAMAX, mislead physicians and the public, and minimize unfavorable studies and findings.

29. FOSAMAX is one of Defendant's top selling drugs, averaging more than $3 billion a year in sales.

30. Consumers, including Plaintiff, Marilyn Hill, who have used FOSAMAX for treatment of osteoporosis, have several alternative safer products available to treat the condition.

31. Defendant knew or should have known of the significant risk of dental and oral complications caused by ingestion of FOSAMAX, but Defendant failed to sufficiently warn consumers, including Plaintiff Marilyn Hill, or the medical community, of such risks.

32. As a direct result, Plaintiff Marilyn Hill was prescribed and ingested FOSAMAX and has been permanently and severely injured. Plaintiff Marilyn Hill requires and will in the future require ongoing medical care and treatment.

33. Plaintiff Marilyn Hill has suffered from mental anguish from, among other things, the knowledge that she will experience life-long complications as a result of the injuries she has sustained from the use of FOSAMAX.

34. Plaintiff Marilyn Hill was prescribed and began taking FOSAMAX in August of 2002.

35. Plaintiff used FOSAMAX as prescribed and in a foreseeable manner for approximately 4 years.

36. As a direct and proximate result of using FOSAMAX, Plaintiff suffered severe osteonecrosis of the jaw.

37. As a direct and proximate result of using FOSAMAX, Plaintiff suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

38. Plaintiff used FOSAMAX which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.

39. Plaintiff would not have used FOSAMAX had Defendant properly disclosed the risks associated with the drug. Alternatively, with adequate disclosure and warnings, Plaintiff would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the ultimate clinical manifestation of the symptoms.

40. Defendant, through its affirmative misconduct, misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking FOSAMAX.

41. As a result of Defendant's actions, Plaintiff and her physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this compliant, and that those risks were the direct and proximate result of Defendant's actions, omissions, and misrepresentations.

42. The running of any applicable statute of limitations has been tolled by reason of Defendant's concealment and Plaintiff's lack of knowledge that Defendant was legally responsible for her injuries.

FIRST CAUSE OF ACTION
NEGLIGENCE

43. Plaintiff restates the allegations set forth above and incorporates the same by reference as though fully set forth herein.

44. Defendant owed Plaintiff, Marilyn Hill, and other consumers, a duty to exercise reasonable care in all aspects of the testing, labeling, marketing, distribution, sale and provision of adequate warnings regarding the use of the drug FOSAMAX to

ensure the safety of the product and to ensure that the consuming public, including Ms. Hill, and prescribing and treating physicians, including Ms. Hill's physicians, obtained accurate information and instructions for the safe use of FOSAMAX.

45. Defendant failed to exercise due care under the circumstances and therefore breached this duty by:

(a) failing to properly and thoroughly test FOSAMAX to ensure its safety before releasing the drug to market;

(b) failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of FOSAMAX;

(c) failing to conduct sufficient post-marketing testing and surveillance of FOSAMAX;

(d) failing to be forthright with the public, the medical community and federal regulators concerning the risks associated with FOSAMAX;

(d) designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

(e) failing to exercise due care when advertising and promoting FOSAMAX; and

(f) negligently continuing to manufacture, market, advertise, and distribute FOSAMAX after Defendant knew or should have known of its adverse effects.

46. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff Marilyn Hill became afflicted with osteonecrosis of the jaw; Plaintiff required and will continue to require healthcare and services; Plaintiff has incurred and will continue to incur medical and related expenses; Plaintiff has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

47. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

SECOND CAUSE OF ACTION
STRICT LIABILITY

48. Plaintiff restates the allegations set forth above and incorporates the same by reference as though fully set forth herein.

49. Defendant manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a defective and unreasonably dangerous condition to consumers, including Plaintiff Marilyn Hill.

50. Defendant designed, manufactured, sold, distributed, supplied, marketed, and/or promoted FOSAMAX, which was expected to reach and did in fact reach

consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

51. Plaintiff used FOSAMAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant.

52. FOSAMAX failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

53. FOSAMAX was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.

54. FOSAMAX was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

55. FOSAMAX was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor was accompanied by warnings adequate to alert consumers, including Plaintiff, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.

56. FOSAMAX was defective and unreasonably dangerous in that it presented such a risk of osteonecrosis of the jaw that an ordinarily prudent company engaged in the manufacture of pharmaceuticals, had it been actually aware of the risk, would not have marketed it.

57. Plaintiff could not, through the exercise of ordinary care, have discovered FOSAMAX's defects or perceived the dangers posed by the drug.

58. Defendant did not provide Marilyn Hill with fair and adequate notice of the danger and possible consequences of using FOSAMAX—specifically the danger and possible consequences of developing osteonecrosis of the jaw.

59. As a direct and proximate consequence of Defendant's conduct, Plaintiff Marilyn Hill sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

60. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

THIRD CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

61. Plaintiff restates the allegations set forth above as if fully rewritten herein.

62. Defendant expressly represented to Plaintiff Marilyn Hill and other consumers and the medical community that FOSAMAX was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

63. FOSAMAX does not conform to Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

64. At all relevant times, FOSAMAX did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

65. Plaintiff Marilyn Hill, other consumers, and the medical community relied upon Defendant's express warranties.

66. As a direct and proximate result of Defendant's actions, Plaintiff Marilyn Hill sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, among other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, and physical pain and suffering.

67. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

FOURTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

68. Plaintiff restates the allegations set forth above as if fully rewritten herein.

69. Defendant manufactured, distributed, advertised, promoted and sold FOSAMAX.

70. At all relevant times, Defendant knew of the use for which FOSAMAX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

71. Defendant was aware that consumers, including Plaintiff Marilyn Hill, would use FOSAMAX for treatment of osteoporosis and for other purposes.

72. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Defendant to sell FOSAMAX only if it was indeed of merchantable quality and safe and fit for its intended use.

73. Defendant breached its implied warranty to consumers, including Plaintiff; FOSAMAX was not of merchantable quality or safe and fit for its intended use.

74. Consumers, including Plaintiff, and the medical community, reasonably relied upon Defendant's implied warranty for FOSAMAX.

75. FOSAMAX reached consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

76. As a direct and proximate result of Defendant's action, Plaintiff Marilyn Hill sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, among other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, and physical pain and suffering.

77. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

FIFTH CAUSE OF ACTION
VIOLATION OF CONSUMER PROTECTION ACT

78. Plaintiff restates the allegations set forth above as if fully rewritten herein.

79. At all relevant times, Plaintiff Marilyn Hill was a consumer within the meaning of the Kentucky Consumer Protection Act, KRS 367.110, *et seq*.

80. By engaging in the conduct described in this Complaint, the Defendant and its agents, apparent agents, servants and/or employees committed acts and omissions, which constitute unfair, false, misleading, and/or deceptive acts or practices in the conduct of trade or commerce, all to the damage of Marilyn Hill.

81. Pursuant to KRS 357.170 and KRS 367.220, Marilyn Hill is entitled to recover reasonable attorneys' fees herein, along with costs and interest for the prosecution of this action, in addition to the other damages set forth in this Complaint.

82. The Kentucky Attorney General is notified of this action pursuant to KRS 367.220.

SIXTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION

83. Plaintiff restates the allegations set forth above as if fully rewritten herein.

84. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had been tested and found to be safe and effective for the treatment of osteoporosis;

85. Defendant knew its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of FOSAMAX to consumers, including Plaintiff, and the medical community.

86. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

87. Defendant's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale and use of FOSAMAX.

88. Plaintiff, Plaintiff's doctors, and others relied upon these representations.

89. Defendant's fraudulent representations demonstrate its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

90. As a direct and proximate result, Plaintiff Marilyn Hill sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, among other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, and physical pain and suffering.

91. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the

rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

SEVENTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT

92. Plaintiff restates the allegations set forth above as if fully rewritten herein.

93. Defendant fraudulently concealed information with respect to FOSAMAX in the following particulars:

(a) Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX was safe and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX and

(b) Defendant fraudulently concealed information which demonstrated that FOSAMAX was not safer than other alternatives available on the market.

94. Defendant had sole access to material facts concerning the dangers and unreasonable risks of FOSAMAX.

95. The concealment of information by Defendant about the risks of FOSAMAX was intentional, and the representations made by Defendant were known to Defendant to be false.

96. The concealment of information and the misrepresentations about FOSAMAX were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

97. Plaintiff, Plaintiff's doctors, and others, relied upon the representations and were unaware of the substantial dental and oral risks of FOSAMAX which Defendant concealed from Plaintiff's doctors and Plaintiff.

98. As a direct and proximate result of Defendant's fraudulent concealment and misrepresentation, Plaintiff Marilyn Hill suffered osteonecrosis of the jaw and was caused to suffer severe and permanent injuries, including pain and mental and physical anguish and suffering, including a diminished capacity for the enjoyment of life, aggravation of preexisting conditions and activation of latent conditions, and a fear of developing other harmful conditions or problems as a result of the injury. Plaintiff has incurred and will continue to incur expense for medical care and treatment due to the injuries caused by FOSAMAX.

99. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

EIGHTH CAUSE OF ACTION—EQUITABLE RELIEF
MEDICAL MONITORING PROGRAM AND PROPER LABELING

100. Plaintiff restates the allegations set forth above as if fully rewritten herein.

101. As a direct and proximate result of Defendant's acts, Plaintiff and other consumers of FOSAMAX face an increased susceptibility to injuries as described herein. This irreparable threat to Plaintiff's and other consumers' health can only be mitigated by the creation of a medical monitoring fund to provide for a medical monitoring program, including: notifying Plaintiff and other FOSAMAX consumers of the defects and the potential medical harm; funding of a program for the surgical treatment

of osteonecrosis of the jaw; funding a study of the long term effects of FOSAMAX within the body of Plaintiff and other FOSAMAX consumers; gathering and forwarding to treating physicians information relating to the diagnosis and treatment of injuries which may result from the product; aiding in the early diagnosis and treatment of resulting injuries; and providing funding for diagnosis and preventable medical treatment, particularly dental and oral monitoring.

102. Plaintiff and other FOSAMAX consumers have no adequate remedy in law in that monetary damages alone do not compensate for the insidious and continuing nature of the harm to her, and only a medical monitoring program which notified Plaintiff and other FOSAMAX consumers and aids in correcting the problems can prevent the greater harms which may not occur immediately and which may be preventable, if proper research is conducted and the health risks are diagnosed and treated before they occur or become worse.

103. Plaintiff and other FOSAMAX consumers have suffered irreparable harm as alleged herein and, in the absence of equitable relief, they will suffer further irreparable harm such as death and severe debilitating injuries from continued retention of the defective drug. Without a medical monitoring program, Plaintiff and other FOSAMAX consumers might not receive prompt and adequate medical care which could prolong their productive lives, increase prospects for improvement and minimize disability.

104. Additionally, Defendant has failed to amend its product labeling information to adequately warn physicians and patients about the risk of osteonecrosis of the jaw. Because of this failure, prescribing physicians are unable to warn patients to be aware of precursor symptoms which, if properly observed and reported to the

physician, could result in discontinuation of FOSAMAX therapy and the prevention or mitigation of osteonecrosis of the jaw.

105. This Court should use its equitable powers, in the interest of public safety and in order to make sure that prescribing physicians have a complete understanding of the risks associated with FOSAMAX, to require Defendant to change its label in a format approved by the FDA to adequately warn physicians and FOSAMAX patients about the risk of osteonecrosis of the jaw and steps which can be taken to prevent or mitigate its occurrence.

PUNITIVE DAMAGES

106. Plaintiff restates the allegations set forth above as if fully rewritten herein.

107. Defendant has repeatedly engaged in a pattern of conduct of deliberately avoiding FDA recommendations, minimizing unfavorable findings and studies, and misleading physicians, consumers and the public at large with regard to warnings concerning public hazards relating to dangerous drugs, including FOSAMAX, that it aggressively marketed.

108. For instance, in March 2000, Defendant completed a study called VIGOR (VIOXX Gastrointestinal Outcomes Research) relating to its prescription cox-2 inhibitor, VIOXX. The VIGOR study showed that VIOXX patients had more than double the rate of serious cardiovascular problems than those on Naproxen, an older non-steroidal anti-inflammatory drug. The study was published in the New England Journal of Medicine.

109. In September 2001, the FDA warned Defendant to stop misleading doctors about VIOXX's effects on the cardiovascular system. Defendant Merck was admonished to stop minimizing the risks of the drug in its marketing. In spite of this

admonishment, Defendant refused to adequately warn physicians and patients about the risk of heart attacks and VIOXX.

110. On August 25, 2004, a representative from the FDA presented results of a database analysis of 1.4 million patients. The analysis demonstrated that VIOXX users were more likely to suffer a heart attack or sudden cardiac death than those taking Celebrex or older non-steroidal drugs. The FDA representative concluded that VIOXX was linked to more than 27,000 heart attacks or sudden cardiac deaths nationwide from the time it came on the market in 1999 through 2003.

111. On August 26, 2004, Defendant released a press statement which refuted the FDA analysis and restated Defendant's support for the cardiovascular safety of VIOXX.

112. On September 30, 2004, Defendant recalled VIOXX from the market, after having to halt the APPROVe study (Adenomatous Polyp Prevention on Vioxx). The study was underway to evaluate the use of VIOXX for recurrent colon polyps. The researchers found an alarming number of cardiovascular events among the drug's users in the APPROVe study.

113. At the same time, Defendant was aware that the FDA, as of August 24, 2004, was advising Defendant to warn about the risk of osteonecrosis of the jaw for its FOSAMAX patients. Because Defendant knew that its blockbuster drug VIOXX was about to be pulled from the market, placing more importance on the over $3 billion annual sales of FOSAMAX, Defendant deliberately chose not to amend its packaging of FOSAMAX to adequately warn of the risk of osteonecrosis of the jaw, fearing that such a warning would result in reduced revenues for its second largest income producer, FOSAMAX.

114. Defendant's acts were willful, wanton, oppressive, malicious, and/or grossly negligent in that Defendant's conduct was carried on with a conscious disregard for the safety and rights of Plaintiff and other consumers of FOSAMAX. Defendant's unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendant in an amount appropriate to punish Defendant and deter similar conduct in the future.

WHEREFORE, Plaintiff Marilyn Hill prays for judgment against Defendant Merck & Company, Inc. as follows:

1. For compensatory damages, including past and future medical expenses; significant pain and suffering and severe emotional distress, past and future;
2. For punitive damages to punish the Defendant for its willful, wanton, oppressive, malicious, and/or grossly negligent conduct and to deter Defendant and others from repeating the injurious conduct alleged herein;
3. For pre-judgment and post-judgment interest;
4. For trial by jury on all issues so triable;
5. For all costs of this suit including reasonable attorneys' fees; and
6. For any and all other relief to which Plaintiff may be entitled at equity or at law, including but not limited to, requiring Defendant to fund a medical monitoring program and compelling Defendant either to withdraw FOSAMAX from the market or adequately warn consumers about the substantial risks associated with FOSAMAX and osteonecrosis of the jaw.

Respectfully submitted,

BAHE COOK CANTLEY & JONES PLC

s/ Shawn E. Cantley
Shawn E. Cantley
(shawn@people-lawyers.com)
John A. Bahe, Jr.
(john@people-lawyers.com)
700 Kentucky Home Life Building
239 South Fifth Street
Louisville, Kentucky 40202
Tel. (502) 587-2002
Fax (502) 587-2006
COUNSEL FOR PLAINTIFF